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Patent Docket P1467R2P2

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  Stephen M. Kelsey et al.  Serial No.: 10/608,626  Filed: June 27, 2003  For: Treatment with Anti-ErbB2 Antibodies	Group Art Unit: 1642  Examiner: To Be Assigned  Confirmation No: 4813  CUSTOMER NO: 09157  Express Mail No. EV 351 924 569 US November <u>5</u> , 2004 <u>Anna Kan</u> Anna Kan
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

(X) **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

0 **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as

checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

(If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.)

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because **a)** ☐ they were previously cited by or submitted to the Office in a prior application Serial No. 10/268,501, filed October 10, 2002 and relied upon in this application for an earlier filing date under 35 USC §120 **and/ or** because **b)** ☐ this application was filed after June 30, 2003. Applicants are no longer required to submit copies of U.S. patents and U.S. patent application publications cited in information disclosure statements for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC §371 after June 30, 2003 **(1276 OG 55)**. Nevertheless, applicants stand ready to provide

copies at the request of the Examiner.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-0" (nucleotide) and "BLAST Results B-1 - B-0" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) (Required)

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: November 5, 2004

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FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark OfficeAtty Docket No.  
P1467R2P2Serial No.  
10/608,626

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant  
Kelsey et al.Filing Date  
27 Jun 2003Group  
1642

## U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
	320	2002/0141993	03.10.02	Ashkenazi et al.		
	321	2002/0192211	19.12.02	Hudziak et al.		
	322	2003/0059790	27.03.03	Jaffee et al.		
	323	2003/0152987	14.08.03	Cohen et al.		
	324	5,648,237	15.07.97	Carter, P.		
	325	6,127,526	03.10.00	Blank		
	326	6,214,388	10.04.01	Benz et al.		
	327	6,267,958	31.07.01	Andya et al.		
	328	6,333,169 B1	25.12.01	Hudziak et al.		
	329	6,333,398	25.12.01	Blank		
	330	6,339,142	15.01.02	Basey et al.		
	331	6,387,371 B1	14.05.02	Hudziak et al		
	332	6,399,063 B1	04.06.02	Hudziak et al		
	333	6,407,213	18.06.02	Carter et al.		
	334	6,417,335	09.07.02	Basey et al.		
	335	6,489,447	03.12.02	Basey et al.		
	336	6,627,196	30.09.03	Baughman et al.		
	337	6,685,940 B2	03.02.04	Andya et al.		
	338	6,719,971	13.04.04	Carter et al.		
	339	6,797,814	28.09.04	Blank, G.		
	340	6,800,738	05.10.04	Carter et al.		

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes No
	341	WO 01/00245	04.01.01	PCT		

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	342	Bast et al., "Selected molecular targets for diagnosis and therapy of epithelial ovarian cancer" <u>Cancer Molecular Biology</u> 1(2):87-93 (1994)
	343	Brabender et al., "Epidermal growth factor receptor and HER2-neu mRNA expression in non-small cell lung cancer is correlated with survival" <u>Clinical Cancer Research</u> 7(7):1850-1855 (Jul 2001)
	344	Maurer et al., "Increased expression of erbB3 in colorectal cancer is associated with concomitant increase in the level of erbB2" <u>Human Pathology</u> 29(8):771-777 (Aug 1998)
	345	Shackney et al., "Intracellular coexpression of epidermal growth factor receptor, Her-2/neu, and p21ras in human breast cancers: evidence for the existence of distinctive patterns of genetic evolution that are common to tumors from different patients" <u>Clinical Cancer Research</u> 4(4):913-928 (Apr 1998)
	346	Suzuki et al., "Growth of human gastric carcinomas and expression of epidermal growth factor, transforming growth factor-alpha, epidermal growth factor receptor and p185c-erbB-2" <u>Oncology</u> 52(5):385-391 (Sep-Oct 1995)

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.